REMARKS

Pending Claims

As a preliminary matter, Applicants point out that the Examiner has issued a restriction based on the originally filed claims, not the claims of the Preliminary Amendment which was filed on September 5, 2006. Applicants also point out that the claims from the Preliminary Amendment are amendments to the Article 34 claims submitted to the Swedish Patent Office and dated December 27, 2005, which were also submitted with a letter upon filing the United States National Phase of this application on September 5, 2006. Accordingly, Applicants request that the Examiner proceed with prosecution based on the claims filed with the Preliminary Amendment on September 5, 2006, i.e., claims 1-15.

Response to Restriction Requirement

The application presents pending claims 1-15. The original claims upon which the Examiner bases his restriction were claims 1-16. In the article 34 claims and the preliminary amendment, claim 2 was incorporated into claim 1. The Examiner has restricted the application into three groups:

Group I: claims 1-13 (claims 1-12 in the Preliminary Amendment), drawn to a method of predicting [the] state of gastric mucosa.

Group II, claims 14 and 15 (claims 13 and 14 in the Preliminary Amendment), drawn to a kit.

Group III claim 16 (claim 15 in the Preliminary Amendment), drawn to a computer readable medium.

The Examiner states that the inventions listed in groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, they lack the same or corresponding special technical features. The Examiner states that the technical feature linking Groups I-III is determination of pepsinogen I (PGI) and gastrin-17 (G-17) analyte concentrations, as well as determining the presence or concentration of Helicobacter pylori. The Examiner asserts that references suggest the use of all three markers. Applicants respectfully traverse.

Applicants respectfully submit that the method of the present invention is not disclosed in the prior art because the method of the present invention is not merely the measurement of the serum values for pepsinogen and gastrin 17 in the presence or absence of H. pylori, and the qualitative diagnosis of atropy of the corpus, atrophy of the antrum, atrophy of the antrum and corpus, and/or atrophic antral H. pylori gastritis. Instead the present method presents a quantitative method for determining the state of the gastric mucosa. Using clinical data which has already been gathered, the method of the present invention calculates actual probabilities that an individual has a given state of disease of the gastric mucosa. The "markers" have been measured before, but the dynamic relationship between the measured amount of the markers and the diseases were not disclosed in Vaananen. (Compare Specification, Figures 2-4, discussed on page 16, line 30 to page 17, line 30 to the broad trends discussed in Vaananen).

Thus, the technical feature that links the claims is not the feature identified by the Examiner, but rather the quantitative analysis method utilizing a data processing system as indicated in claim 1, and as embodied in a computer program as recited in claims 13 and 15. The Examiner has not even attempted to show that this feature is described in the prior art. Thus, the entire basis for the Examiner's restriction requirement is improper. Applicants submit that Groups I-III share the special technical feature of a quantitative method for predicting the state of the gastric mucosa. Accordingly, Applicants request that the Examiner rejoin Groups I-III.

However, without conceding to the Examiner's restriction, in order to be compliant, Applicants herein elect Group I, claims 1-13 (claims 1-12 from the Preliminary Amendment) drawn to a method of predicting [the] state of gastric mucosa.

Election of Species

The Examiner states that the Application contains directed to more than one species of the generic invention. The Examiner would require election of a species gastric mucosa to be assessed. Applicants respectfully traverse.

As a preliminary matter, the Examiner is required by MPEP 1893.03(d) to "(1) list the different groups of claims and (2) explain why each group lacks unity with each other group." The

Examiner has provided no rationale for why the class of gastric mucosa should be subject to an election of species. Accordingly, Applicants submit that the Examiner's election of species requirement fails as a matter of law.

Further, the Examiner's election of species is not logical in view of the claimed invention. The method of the present invention is directed to determining the probability that the gastric mucosa of an individual belongs to at least one gastric mucosa class. It is not a simple calculation that one either has a type of gastric mucosa or not. Instead the claimed method accounts for the intercorrelated relationship between the multiple markers and the probability that an individual's mucosa is one of multiple classes of gastric mucosa.

For instance, holding the measured G-17 value constant, an individual could still have a significant risk of having any one or more of the four gastric classes (or be completely normal), depending on the amount of PGI and H. pylori antibody measured. (See figure 2, discussed on page 16, line 30 to page 17, line 30 of the Specification).

This is further evidence by a comparison of Example 3 to Example 5 of the Specification, where G-17 values are 20 pmol/l and 21.7 pmol/l (respectively) (Specification, page 13, line 17 and page 15, line 2). In Example 3, the claimed method would suggest that the individual would be diagnosed with atrophic corpus gastritis, and an increased risk of gastric cancer, whereas Example 5 would suggest that the individual would be diagnosed as normal. (See page13, line 29 and page 15, line 14).

Accordingly, Applicants request that the Examiner withdraw the election of species. **That said, in order to be fully compliant, Applicants herein elect antrum atrophy for initial examination. All of claims 1-15 read on this species.**

The Examiner would also require an election between a type of Helicobacter pylori marker. Applicants submit that there is virtually no difference between antigen and antibody detection, and request that the Examiner withdraw the election of species. **However, in order to be fully compliant, Applicants herein elect H. pylori antibodies (present claim 7) for initial examination. Claims 1-7 and 9-15 are readable on this elected species.**

For both the gastric class and the H. pylori marker, Applicants explicitly reserve their rights under MPEP §803, which provides that, once claims directed to the species elected for initial examination are found allowable, the Examiner must expand the search and examination to encompass other species and, ultimately, Applicants' generic claims.

Conclusion

An early and favorable first action on the merits is earnestly solicited.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson (Reg. No. 30,330) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a one (1) month extension of time for filing a reply in connection with the present application, and the required fee of $65.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: March 16, 2009

Respectfully submitted,

Leonard R. Svensson
Registration No.: 30,330
BIRCH, STEWART, KOLASCH & BIRCH, LLP
650 Town Center Drive
Suite 620
Costa Mesa, California 92626-7127
(714) 708-8555
Attorney for Applicant